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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,901	10/18/1999	JENNIFER E. VAN EYK	1997-023-04U	2043

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/419,901	VAN EYK ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,15-18,20-28,31,34,35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,15-18,20-28,31,34,35 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/05 has been entered.

Amendment Entry

2. Applicant response and amendment filed 5/18/05 is acknowledged. Claims 1-7, 20, 22, 35 and 37 have been modified. Claims 8-14, 19, 29-30, 32-33, 36 and 42-68 have been canceled. Currently claims 1-7, 15-18, 20-28, 31, 34-35, 37-41 are pending and under consideration.

3. Rejections and/or objections of record not reiterated herein have been withdrawn.

REJECTIONS WITHDRAWN

Double Patenting

4. Claims 1-7, 15-18, 20-28, 31, 34-35, 37-41 are withdrawn from provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/115,589 because the claims have been cancelled and the newly presented claims no longer read on the subject matter of the instant claims.

NEW GROUNDS OF REJECTION

Sequence Non-Compliance

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Sequences are recited in the specification in Table 1. However the sequences have not identified by a sequence identification number.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-7, 15-18, 20-28, 31, 34-35, and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The claims are directed to methods of assessing muscle damage via the measurement of post-translationally occurring myofilament protein modification products being a chemical adduct of troponin I, troponin T, troponin C, α-actinin, actin, tropomyosin, desmin, myosin light chain 1, myosin light chain 2, and myosin light chain 3. However the specification does not establish normal or threshold values in each test sample in order to compare the detected myofilament protein modification proteins as a measure of muscle damage. In other words a comparison of normal ranges is required to assess muscle damage. The mere detect of the presence of the claimed protein in and of itself does not indicate muscle damage when the normal protein content is unknown. Therefore one of ordinary skill in the art would not be able to use the invention without undue experimentation

Specifically, the specification does not teach the measurement of normal or healthy muscle values for the claimed protein markers nor does it establish individual control ranges to compare the measure against the detected myofilament protein modification proteins as a measure of muscle damage. The prior art teaches that normal protein comparison is needed to evaluate protein content. For example, see Bodor et al. Circulation, Vol.96, No.5, September 2, 1997, pages 1495-1500.

The instant disclosure has not addressed the issues taught in the prior art as crucial to the discovery of a biopolymer marker.

The nature of the invention- the invention is directed to muscle damage protein modification markers.

The state of the prior art- the prior art discloses that control or normal protein content is needed to determine proteins assessment in muscle damage.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed protein modification marker is useful in assessing muscle damage.

The amount of direction or guidance present- appropriate guidance is not provided by the specification for the claimed myofilament protein modification products.

The presence or absence of working examples- working examples are not provided in the specification that exemplify the protein modification products as measures for muscle damage by way of comparison to normal values or controls.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the myofilament protein modification products.

*The relative skill of those in the art-*the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to methods of assessing muscle damage via the measurement of myofilament protein modification products.

While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled. This is not the case in the instant specification.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue.

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966).

While every aspect of a generic claim does not have to be carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genetech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001. That requirement has not been met in this specification with respect to the detection of myofilament protein modification proteins as a measure of muscle damage.

Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

7. Claims 1-7, 15-18, 20-28, 31, 34-35, 37-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the detection of troponin I, troponin T, troponin C, α-actinin, actin, tropomyosin, desmin, myosin light chain 1, myosin light chain 2, and myosin light chain 3 myofilament chemical adduct modification products occurring post-translationally in cardiac muscles (see examples in specification on pages 31-50), it does not reasonably provide enablement for any and all muscle damage (as recited in the claims).

The disclosure exemplifies heart related tissue assessment of the protein modification products but does not evaluate the protein modification products in other muscle tissue. The prior art teaches that muscle proteins are located in various diverse tissues and the protein content of these muscles differ significantly. For example, see Thompson et al. (Cell. Signal. Vol.10, No.1, pages 1-11, 1998) wherein various diverse proteins are taught to be involved in skeletal muscle damage (see pages 5-8). Chan et al. (Biosensors and Bioelectronics, 20, 2005m 2566-2580) teach that protein specificity is important in detecting tissue injury and specificity for muscles other than the heart has not been shown in the disclosure. Accordingly the demonstration of the claimed myofilament chemical adduct modification products occurring post-translationally in tissues other than heart is required to meet the full breathe of the claims.

8. For reasons aforementioned, no claims are allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/22/05

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